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USAMRMC ltr, dtd 15 May 2003

AD ______________

Award Number: DAMD17-99-1-9053

TITLE: Evaluation of Optical Sonography TM for Real-Time Breast Imaging and Biopsy Guidance

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REPORT DATE: August 2000

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	August 2000	Annual (19 Jul 99 - 18 Jul 00)

4. TITLE AND SUBTITLE
Evaluation of Optical Sonography TM for Real-Time Breast Imaging and Biopsy Guidance

5. FUNDING NUMBERS
DAMD17-99-1-9053

6. AUTHOR(S)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

This report contains colored photos

12a. DISTRIBUTION / AVAILABILITY STATEMENT
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13. ABSTRACT *(Maximum 200 Words)*

Significant progress has been made over the last decade to detect and diagnose breast disease using several imaging modalities. However, x-ray, reflective ultrasound and MRI have limitations and fully satisfactory imaging methods have not been identified. Breast imaging is ready for a method using non-ionizing radiation, less compression, and which holds the possibility of detecting lesions within the dense breast and differentiating subtle variations in tissue properties. The purpose of this study is to review the merits of Optical Sonography for breast imaging. This paper describes system modifications and results of laboratory studies conducted during the first year. Major accomplishments include the design and development of a prototype system focusing on a patient interface specifically for breast imaging, the incorporation of a 12-bit CCD camera and associated video chain hardware and software, the completion of automated image data collection and storage, and system optimization. System characterization tasks establish baseline data for spatial resolution, dynamic range, depth of field, acoustic intensities, and system modulation transfer function. In addition several computational imaging procedures were developed for system characterization and image enhancements. As a result of these studies, a number of additional improvements to key components have been identified and are being implemented.

14. SUBJECT TERMS
Breast Cancer

15. NUMBER OF PAGES
16

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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INTRODUCTION

The *primary objective* of this study is to evaluate the suitability of Optical Sonography™ for detection and characterization of breast disease. Optical Sonography™ is a method of ultrasound imaging that utilizes a coherent laser beam to illuminate an interference pattern formed by a reference sound wave and the transmitted acoustic wave through an object. The image is produced from the perturbations in both phase and amplitude of the acoustic beam (dependent on the acoustical properties of the object) at the surface of a detector. The interference pattern generated is illuminated by reflected light from a collimated laser beam. Since reconstruction is performed optically, image formation is produced in real time. The method, called acoustical holography, was the subject of intense research in the 1970's and 1980's for both medical and industrial applications.[1-7] The widespread availability in these earlier years of general-purpose, hand-held, real-time, medical ultrasound systems likely diminished interest in the more cumbersome dedicated systems. Furthermore, the quality, cost and availability of appropriate optical systems and large area transducers at the time substantially reduced the practicality of acoustical holography. Although a number of potential medical applications were explored, one promising area identified for acoustical holography was diagnostic breast imaging for breast cancer management.[4,7] With the sharp increase in incidence of breast cancer, the potential importance of this application may be even better appreciated today than it was in the 1970's. The *purpose and scope* of this study in its first year was to review the merits of Optical Sonography by assembling a prototype system incorporating several new developments in design, including ones not available to early investigators in the field. This annual report describes modifications to the prototype system for breast imaging and results of system characterization studies and image quality measurements.

BODY

Materials and Methods

The Optical Sonography system (Figure 1) is based on a design described in detail elsewhere with several modifications.[8,9] The system uses three matched, large area transducers (77.42 cm^2): two object transducers rotating at a slight angle to enhance edge definition and illuminate the object; and one serving as the reference beam. A sequence of 12 discrete frequencies from 2.45-3.0 MHz is transmitted with equalized output at a rate of 120 sec^{-1}. The interference pattern generated at the detector is illuminated with a laser and viewed in real time using a 12-bit digital CCD camera. Patient imaging is usually performed with real-time averaging of from 4 to 32 video frames. The acoustic lenses have an effective acoustic aperture of 20.3 cm, an adjustable focus range throughout the object imaging distance (approximately 15 cm) and a system f-number of 1.875.

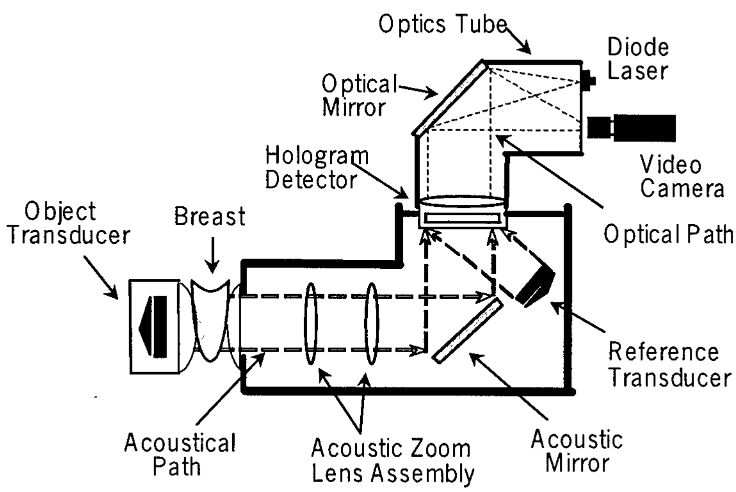

Figure 1. Optical Sonography System Diagram

As part of this study, laboratory measurements were made of resolution, modulation transfer function, dynamic range, distortion, effective focal plane thickness, acoustic power output, and artifacts.

The study prescribed specific modifications to the system hardware and software. A review of available CCDs was completed and a 12-bit camera was selected, installed and tested. Other necessary modifications coupled to the CCD installation included a new image acquisition board and digital I/O. A design review was completed on the proposed patient interface. It was then fabricated, installed and tested during the initial months of the study. This interface included a padded table, similar to a biopsy table, where one breast was lowered into the acoustic beam through an access hole. The breast was suspended in a water bath positioned below the table and was stabilized for imaging through use of two, acoustically non-reflective compression plates mounted within the water bath. Images were acquired and comparisons were made with images obtained using a previous patient interface design.

Commercially available phantoms were purchased and several more were developed in-house to measure specific performance features of the system and to mimic several physical and acoustic properties of the breast. Included was the dual modality biopsy training phantom Model No. 18-299 sold through Nuclear Associates. This phantom was developed for use in x-ray mammography and reflective ultrasound, and designed specifically for needle biopsy. It is marketed as having "physical density and attenuation characteristics which accurately simulate that of an average 45 percent glandular breast (BR-12 equivalent) under both x-ray and ultrasound."[10] An ATS Model bb-1 urethane rubber phantom was also procured. The acoustic properties of this phantom include sound speed of 1405 m/s and an attenuation of 0.218 dB/cm/MHz. Other phantoms were fabricated in an attempt to reproduce the scattering effects seen in the breast and to create isolated targets that represented acoustic properties of various embedded lesions. The phantoms developed in-house ranged from single line targets and step wedges to gel phantoms made to mimic physical characteristics of the breast. Recipes for these latter phantoms are described in the literature.[11]

Initial studies addressed image acquisition and processing techniques to identify the highest practical resolution and dynamic range to collect information not recorded by the 8-bit video camera and laser combination previously employed. Other than the averaging of frames during image acquisition, the images produced to date using the Optical Sonography system have not undergone processing. Initial efforts to explore the application of software algorithms to measure and/or enhance image quality are now underway. During the first year of this study a series of computational imaging procedures were developed to: 1) provide quantitative systematic analysis of the fundamental imaging system performance, including measurements relating to frame sampling integration error, system image depth-of-field, axial and cross-field image resolution and aperture illumination characteristics; and 2) optimize the output imagery by applying minor corrections for acquisition system cross field illumination effects (flat-fielding), provide the means to combine multiple component views of the breast into a single full view (which we call stitching), and provide variable level image enhancement to improve the system focus.

In preparation for data collection, a procedure for storage and retrieval of images was developed, where images from the Optical Sonography system were archived along with corresponding scanned images of x-ray mammograms and reflective ultrasound images when available. Subject data collection and pre-screening evaluation sheets were developed and archived along with medical reports. It should be noted that medical reports and films were not always available, particularly for normal subjects. Normal subjects were imaged in this first year to support image quality assessment activities, system characterization activities, and evaluation of the patient interface.

Results

Several modifications to the system hardware and software were implemented in the first year. One modification involved the selection and installation of a CCD. In the process of matching candidate CCDs to the system, the entire video chain from image production to storage and retrieval was evaluated. Performance specifications were developed. Included was the desire to capture accurately and in real-time all data contained within the hologram, with time left to process, store, and display these data simultaneously. Holograms are being produced at a rate of 120 per second. To illuminate the pattern, and capture, process, store and display the image poses a fairly significant challenge at these rates.

As a review, the original configuration of the system included a 25W pulsed laser diode at 904 nm, an analog tube camera from RCA with an IR sensitive tube, and a VCR and video monitor. Limitations in the system included a visible pattern resulting from the laser field, poor signal to noise ratio, and analog data path from camera to VCR to monitor that was noisy, and CCD pixels were not square, which yielded a stretched scaling to the image. In addition, a digital image format was desired for image processing and transmission. In a desire to move to a digital environment, reduce noise to a minimum, increase the dynamic range, and maintain a real-time chain, several hardware and software modifications were made. This included a digital acquisition and processing board, and a SMD 1M15 camera with 1024x1024 pixels and 12-bit 15fps digital output. This camera most closely matched the 904 nm laser diode spectral response. While 30fps were thought initially to be desirable, evaluation showed that this frame rate would be adequate for static breast imaging and allowed for the incorporation of frame averaging algorithms at slower rates. The camera was installed, supporting software was written, and the video chain was integrated and tested.

Several laser diodes were tested for laser illumination uniformity and brightness. The high power 60W diode was selected as providing best illumination pattern along with brightest image. Illumination was aligned to the top of the image area providing an image to the water bath level. Increased brightness allowed the camera gain to be reduced by a factor of 4 back to unity gain. Images were acquired at several source transducer angles. Results showed the smaller acute angles between source transducers yielded improved spatial resolution. The tradeoff was a reduced field of view, approximately 3 in diameter at a minimum acute transducer angle to reach the detector surface. Work continues in this area of transducer, acoustic lens, laser and detector matching to maximize field of view and obtain illumination uniformity while accessing the chest wall.

Modifications to the patient interface included the completion of the proposed table, table motion and compression plates. Figure 2 shows the installed table in operation. The former patient interface incorporated water-filled latex pillows in contact with the breast, providing acoustic energy continuity within the system acoustic path. This former interface limited the field-of-view and did not allow for visualization of the boundaries of the breast. The system was modified to include a water bath system yielding visual access to the outline of the breast. Figures 3 and 4 how the extent of visual access to the breast using both the former pillow and current water bath systems. Scanning through the breast was completed by focusing from the superior aspect of the breast to the inferior aspect via acoustic lens adjustments. Additional software modifications made during this study lead to the automation of the acoustic lens adjustment features. This resulted in imaging modes for: 1) scanning through layers of the breast by progressively moving the focal plane, referred to as the autoscan; and 2) scanning a single focal plane with time dependent activity, referred to as the cine loop. Images were acquired and viewed in real-time and saved directly to disk, with subsequent access as video sequences or as still image frames.

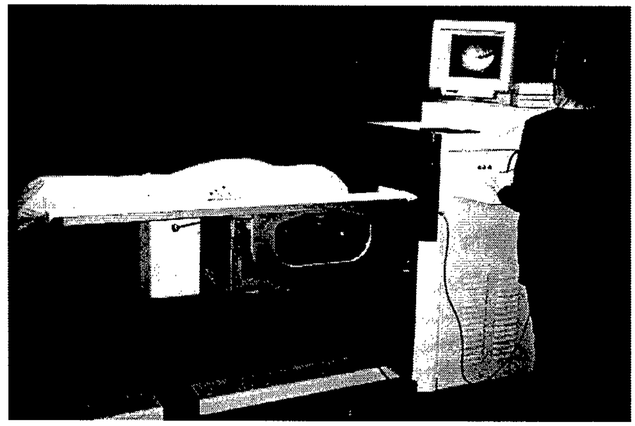

Figure 2. Installed patient table with breast interface

Figure 3. Breast image using water filled pillows

Figure 4. Breast image using water bath showing outline of breast

Using the Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment,[12] and working with the FDA, ADI is developing an acoustic output test methodology. In preliminary tests acoustic intensity output was measured with an NBS-traceable hydrophone at the entrance point to the patient with maximum transducer power for the swept-frequency beam (2.45-3.0 MHz) with the following results: I_{spta} 65.33mW/cm, I_{sppa} 6.41 W/cm^2, I_m 6.41 W/cm^2, $MI_{2.6}$ 0.27. System limiting resolution was estimated using a line-pair target with decreasing line thickness and separation (Figure 5) For a swept-frequency beam from 2.6-3.0 MHz, the minimum resolution was 0.5 lp/mm in water. The line spread and modulation transfer functions for a small line target in water are shown in Figure 6 This MTF approximates a sinc function at 2.45 MHz, the low end of the transmit bandwidth. The focal plane sensitivity in the z-axis is shown in

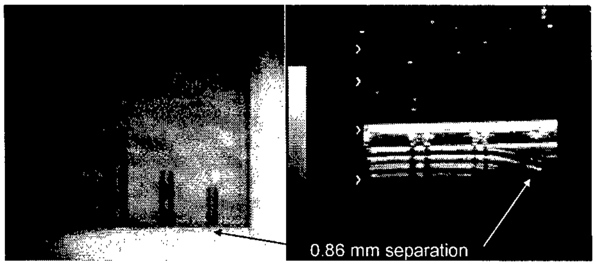

Figure5. Resolution block by Optical Sonography (left) and reflective ultrasound (right).

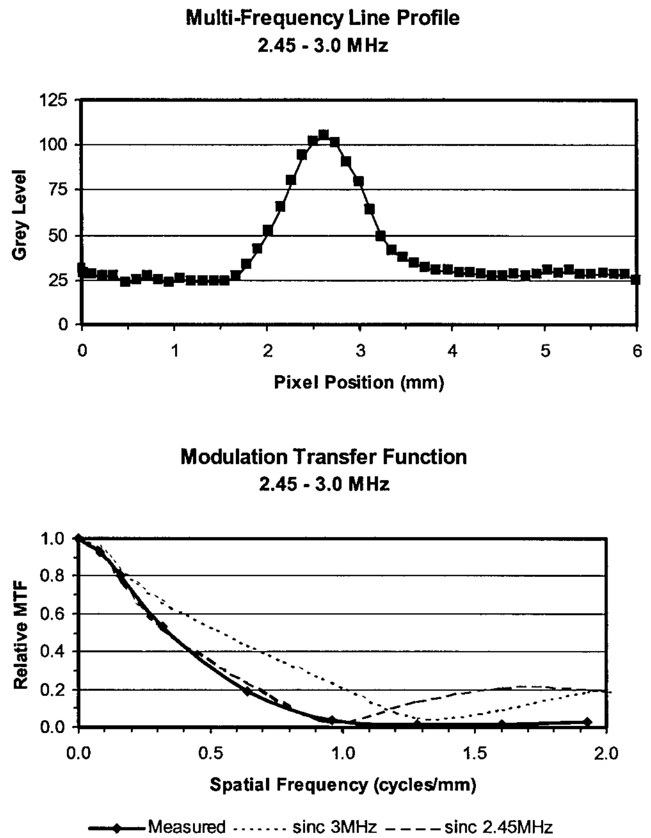

Figure 6. Line spread function and MTF for line target in water.

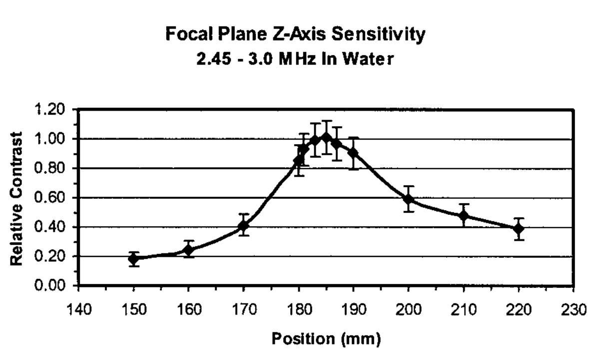

Figure 7. Effective focal plane thickness is ~40 mm.

Figure 7 that indicates an effective thickness of about 40 mm. Total system dynamic range was computed and found to be 1500:1 with the 12-bit camera in a linear mode.

Several phantom studies were completed. Hydroxyapatite crystals with 5% carbonate were sieved to size ranges that represented calcifications and were suspended in castor oil (velocity 1540 m/sec, density 960 kg/m3) to approximate breast micro-calcifications. Crystals from 0.425-1.18 mm in diameter were resolved well, and single crystals ranging from 0.210- 0.425 mm were detected in acoustic zoom mode. Needle visibility was examined with both a 14-gauge biopsy needle (measures as 2.1 mm body diameter) and a 0.6-mm needle. In each case the needle tip was clearly visible throughout the dynamic imaging sequence as it was slowly inserted into a Nuclear Associates tissue-equivalent breast biopsy phantom (Figure 8). Two physicians were consistently successful engaging the target masses with each pass.

Work continues on in-house produced phantoms. By varying quantities of talc, n-propanol, and oils, we have produced tissue mimicking gelatins that vary in velocity from 1505 to 1554 m/s with densities that are very close to one another. Lesion simulations were constructed from these materials and embedded in a substrate that had a physical shape and scattering characteristics similar to the breast. The intent was to investigate the sensitivity of the imaging system to detect differences in these simulated lesions within their respective phantom substrates under varying image conditions (intensity, camera setting, amount of compression, etc.). These tests are on-going.

Progress on the development of several computational imaging procedures is presented next along with preliminary results. As the study progresses, these procedures will be refined. The first procedures address system characterization.

Figure 8. Nuclear Associates Dual Modality phantom showing simulated biopsy using 14 gauge biopsy needle

Frame Integration Analysis: The Optical Sonography imaging system time integrates multiple images to minimize non-uniform illumination and noise effects introduced by the rotating source transducers (120 rpm, 1.7% duty cycle, pulsed at 120Hz, every 8.3 ms for 100 mico-sec.), the laser and the digital camera (with a framing rate of 15 frames per second synced to the transducer pulse). In order to determine the variance in image quality and systemic noise, a procedure was developed to compare multiple images taken during the normal duty cycle (8 images are integrated per frame with each frame captured every 0.266 seconds). This was done by fitting each of the captured images together in a linear least squares fashion and then mapping the variance between the images. This variance was computed for 28 different sets of breast images (3 images per set) and on the average, the maximum integrated image variance was shown to be +/- 5.4%. Figure 9 illustrates pseudo-color mapping of the variance between 3 images.

Depth-of-Field and Image Resolution Analysis: The imaging system employs several focusing lenses to optimize resolution of a singular planar slice within the imaged object. As such the system has an optimal focal plane with an associated depth-of-field (DOF). To determine this optimal focal plane and the extent of its relative DOF, it is necessary to have basic tools that measure the level of focus (resolving ability) within the image. This is accomplished in a three step process based on measuring (i) the absolute resolution through MTF procedures (ii), measuring the axial resolution change and (iii) measuring the relative cross field changes.. From the known absolute resolution measurement at the center and the coupled axial scan and cross field measures, the full aperture resolution, the spatial variance in the resolution, the orientation and flatness of the imaging focal plane can be measured.

a. Axial line Scan Resolution: A series of computational procedures were developed to measure the system MTF of an axial imaged set of target line patterns (which provides an absolute resolution measurement relative to the imaged target spatial pattern) and to measure the line target 'level of detail' content across the image axis for comparative analysis with the cross field measurements. This level of detail measurement is based on the integration of the spectral energy density (SED from 0.5 to 1.0 the Nyquist limit) of a series of $2^n x 2^n$ samples (n=5 to n=8) taken at each point along an axial target line as seen in Figure 10.

b. Cross Field Resolution Scan: Since most imaging systems evidence some form of field aberrations, the ability to determine their effect on the imagery and their variance as a function of the DOF is important. The applied procedure involves the transformation of the imaged aperture into a detail content mapping. As in the line scan procedure, the amount of focused detail is measured as the positional local-area high frequency content (integrated local area SED) across the entire machine aperture (Figures 11 and 12.) In Figure 13 the Windows NT interface for the computation of the Cross Field Resolution is shown. Here the cross field mapping is shown on the left and the absolute amplitude of the detail content (SED), averaged across the open aperture per frame, is plotted on the right. As the target is moved about the focal plane and a new image acquired and processed, the change in resolution is evidenced within this plot. This enables the physical identification of the optimal location of the focal plane (for a lens setting) and the measurement of the extent and range of the DOF.

Image Illumination Effects: The basic system illumination is generated by a rotating pulsed rectangular transducer with the output image frame constructed from a time averaging of 8 images acquired within 0.266 seconds. And since the imaging system is holographic in nature employing a reference signal and an imaging laser with its own angular field distribution, these effects compound to create interference patterns and irregularities in the illumination field across the open aperture. A series of procedures were developed to quantify the relative cross field illumination within the open aperture. This was accomplished by generating a series of light level (intensity) mappings similar to topographical mappings in satellite imagery (Figures 14, 15, 16).

The following procedures and results address some initial activities to investigate image enhancement.

Image Flat-fielding: To optimize the image content of the optical sonogram, the basic image is corrected for the variance in cross field illumination by a comparison of the image to the illumination pattern taken from a reference background of the open aperture field. The correction is based on the assumption that the attenuation of the illumination is proportional to the density of the structure in a logarithmic fashion. This procedure also enables the elimination of any part of the image not containing part of the breast (open aperture). Figure 17 presents an initial "optimization" of a breast image by comparative attenuation between an imaged breast and its background reference image. The original imaged breast is shown in the upper left corner and the background reference is shown in the upper right corner. The results of the flat-fielding operation are shown below the original image in the lower left corner and an intensity inversion of the flat-fielded image is shown in the lower right hand corner.

Image Stitching: It is often found that images of large breasted woman need to be taken piece-wise since the full breast cannot fit entirely within the effective imaging field. Several images are taken of the breast (typically 3, a lateral, mid and medial view) with a minimum of 5 to 10% overlap to allow for overlap alignment. A series of registration and melding procedures are then employed to combine these image components into a single ‘stitched’ full sized view. This is accomplished by (i) flat-fielding each of the component images, (ii) normalizing the components to the same intensity (contrast) scale, (iii) overlaying and aligning the images on top of each other and computing a level of alignment associated with position (the images are moved around to find the best level of alignment and respective placement (Figure 19), (iv) boundaries are then assigned between each component image within the overlap region (based on detail content) and (v) each piece is then cut out of its component image and the boundary line between the segments is melded by a linear regressive boundary fitting function (Figure 20).

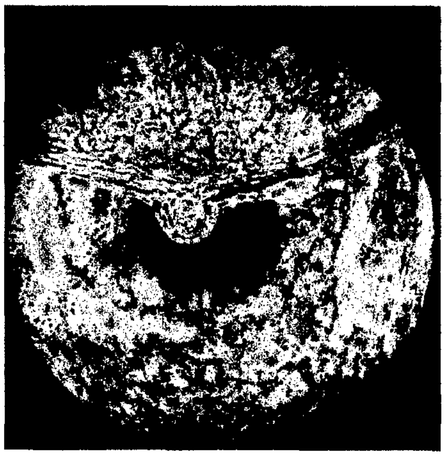

Figure 9. Pseudo-color mapping showing variance between 3 images

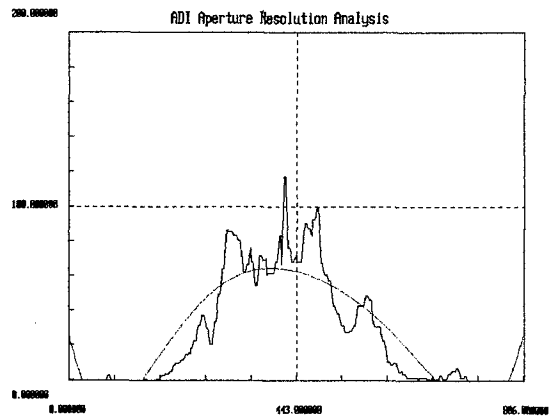

Figure 10. Line scan level of detail plot showing relative amount of detail across image

Figure 11. Resolution aperture mapping showing relative amount of detail across system aperture using single axial line target

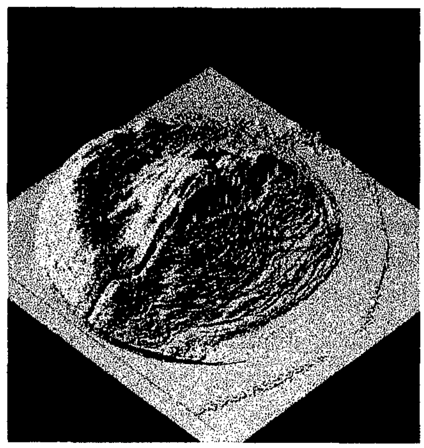

Figure 12. A 3D visualization of the resolution aperture mapping in Figure 11 with elevation representing detail magnitude

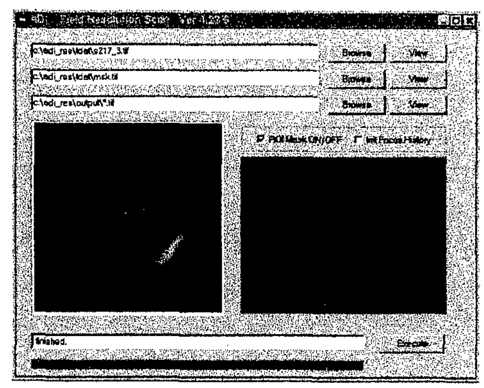

Figure 13. NT interface developed for computation of the cross field resolution

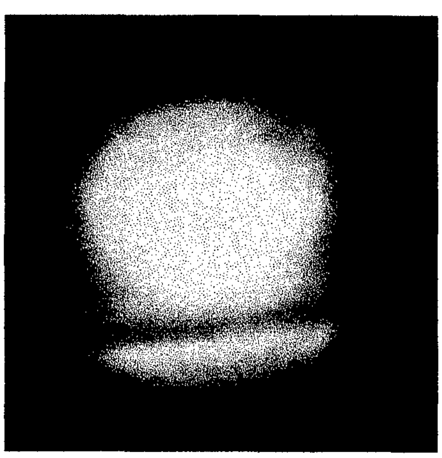

Figure 14. System open aperture showing interference ring generated by laser

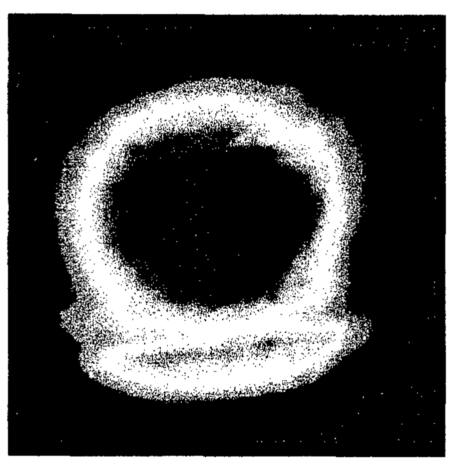

Figure 15. Pseudo color plot of open aperture

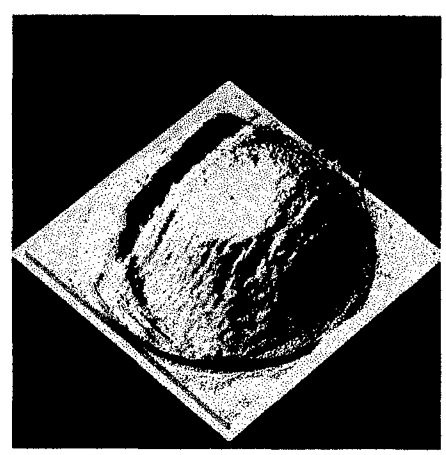

Figure 16. 3D visualization of aperture illumination with elevation representing illumination intensity

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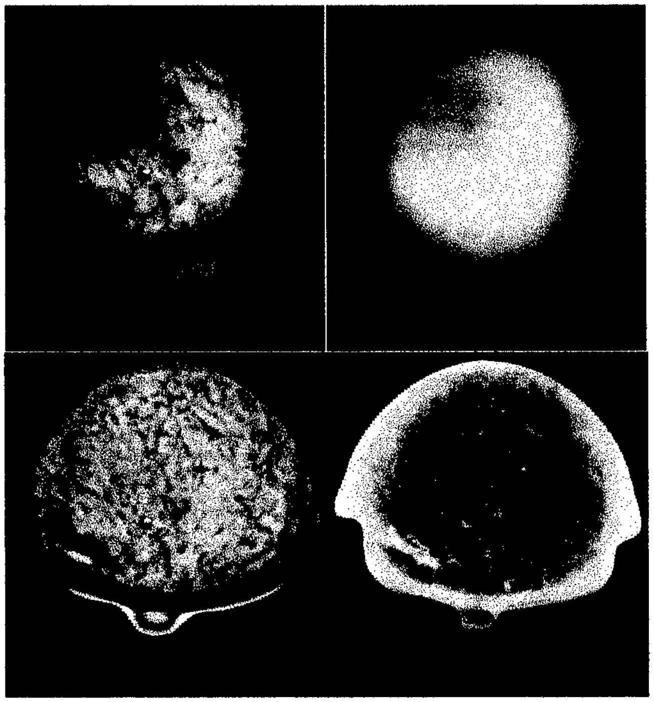

Figure 17. First attempts at optimization of breast image by comparative attenuation between an imaged breast and its background reference image. Original imaged breast is shown in upper left corner and background reference is shown in upper right corner. Results of flat-fielding operation are shown below original image in lower left and an intensity inversion of the flat-fielded image is shown in the lower right.

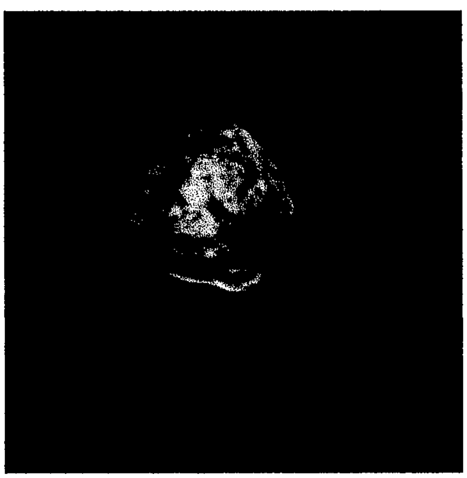

Figure 18. Overlay of the medial, mid and lateral breast images (partial views) after structural registration

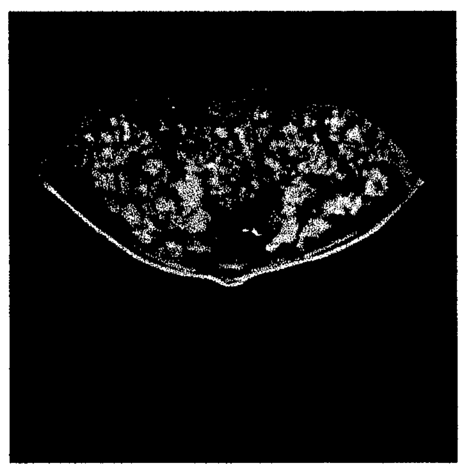

Figure 19. Full field image of the breast generated by "stitching" component segments from 3 partial views

KEY RESEARCH ACCOMPLISHMENTS

- System modifications
  - 12-bit CCD camera and associated video chain hardware and software modifications`
  - Patient interface for breast imaging
  - Completion of automated image data collection for image sequences
- System optimization
  - Camera settings
  - Laser/camera integration
- System Characterization
  - Spatial resolution and high contrast event detection
  - Dynamic range
  - Depth of field
  - Acoustic Intensities
  - System modulation transfer function
- Computational imaging procedures for system characterization and image enhancements
- Database development for pre-clinical data collection and evaluation forms

REPORTABLE OUTCOMES - none to date

CONCLUSIONS

Preliminary studies indicate the Optical Sonography™ method has unique potential for detecting, differentiating, and guiding the biopsy of breast lesions using real-time acoustical holography. During the first year of the BCRP study, baseline characterization was completed and promising applications were identified. Results of these activities show that several attributes of the system design will require modification to enhance its suitability for clinical use, and more work is needed to establish system utility.

Several modifications to the system were implemented during the first year. Included was the development of a patient interface for breast imaging, implementation of a 12-bit CCD camera and development of related digital I/O, optimization of the video chain, and automation of image data collection features. Patient interface features are important to the placement and imaging of subjects and for visual access to the breast. Although it greatly simplifies coupling the large source beam to the patient, provides a larger field of view, and facilitates manipulation of tissue by the clinician, the water bath may be unacceptable for many procedures (e.g., access for needle biopsy). Additional alternatives will be explored. Improvements in video chain and data collection features will aid in determining the sensitivity of the system to variations in tissue acoustic properties, and in the collection of image "slice" data for evaluation. Laboratory tests performed during the first year established baseline data to which future enhancements can be compared, and defined procedures for system characterization. Computational imaging procedures outlined in the first year will provide guidance for image processing activities that may substantially improve future images.

Laboratory results suggest that there are several refinements to the acoustic path and data acquisition subsystems that will significantly improve image quality by enhancing detection of small features and increasing edge delineation. Improvements to the uniformity in background illumination are being pursued through laser diode selection, lensing the diode output and by achieving uniform source transducer output at the point of beam overlap. This will improve the raw image and reduce the need for flatfielding as an image postprocessing activity. A larger field of view is desirable to achieve an image of the entire breast. Results of studies to date show that the combination of larger source transducers and optimum overlap of the output beam is perhaps the best alternative. However, study results also indicate that the post processing technique of "stitching" will provide the entire breast image if larger source transducers are not immediately achievable. Results from cross-field resolution tests indicate that acoustic lens configurations do not meet original fabrication specifications. The result is an image where spatial resolution is degraded in the periphery. Precision machining is being implemented to improve lens profiles and thus, cross-field resolution values.

While data obtained from the prototype Optical Sonography™ system must be considered preliminary, it should be noted that this technology provides high resolution images while overcoming some of the limitations attributed to more conventional imaging modalities. Data collection in the next two years is intended to verify that this low cost, non-ionizing imaging modality differentiates the gross as well as subtler variations among tissues, and delineates well the edges of breast structures, including cysts, ducts, fibroadenomas, and cancers. Optical Sonography™ provides a large field-of-view which is necessary for screening and has an acoustic zoom feature to enlarge areas of interest without loss of resolution. Its real-time features are advantageous for possible applications to image-guided interventions.

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DEPARTMENT OF THE ARMY
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REPLY TO
ATTENTION OF

MCMR-RMI-S (70-1y) 15 May 03

MEMORANDUM FOR Administrator, Defense Technical Information Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

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FOR THE COMMANDER:

Phyllis Rinehart

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